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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,207	01/08/2001	Michael Stuke	HUBR1165 100	5279

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EXAMINER	
ROSSI, JESSICA	

ART UNIT	PAPER NUMBER
1733	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MKR

Office Action Summary	Application No.	Applicant(s)	
	09/647,207	STUKE ET AL.	
	Examiner	Art Unit	
	Jessica L. Rossi	1733	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/2/04, Amendment*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24,26-34,36,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,26-34,36,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment dated 9/2/04. Claim 37 was cancelled. Claim 46 was added. Claims 23-24, 26-34, 36, and 45-46 are pending.

2. Support for some of the limitations added to claim 23 can be found on p. 4, lines 24-29 and in cancelled claim 37.

3. Support for the limitation pertaining to cooling to about 40°C in step (d) of new claim 46 is found on p. 5, lines 1-3.

4. The 112 2nd paragraph rejection set forth in paragraph 4 of the previous office action dated 3/4/04 is withdrawn in light of the present amendment to claim 23.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23-24, 26-34, 36, and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While the specification has support for cooling down to a temperature of about 40°C, as set forth in claim 46, it does not have support for cooling down to a temperature of 40°C, as set forth in claim 23 (see p. 5, lines 1-3 of specification).

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 23-24, 26-29, 31-34, 36, and 45-46 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al. (US 6176962; of record) in view of McReynolds (US 5882465; of record) and Oshida et al. (US 3997386; of record), as set forth in paragraph 6 of the previous office action dated 3/4/04.

With respect to claims 23 and 46, Soane is directed to adhesive-free bonding (column 5, lines 21-23) of microfluidic devices. The reference teaches preparing a polymeric substrate 12, which has depressions forming microchannels 21 and 23, and applying a polymeric cover 14 to the substrate by uniform pressure (Figures 5-6; column 2, lines 39-46 and 58-65). The reference teaches heating the substrate and cover to 2-5°C above the glass transition temperature of the substrate and cover, while still applying pressure to the cover, and holding the substrate and cover at this temperature of 2-5°C above the glass transition temperature (column 2, line 63 – column 3, line 4). Soane teaches slowly reducing/cooling the temperature of the substrate but fails to disclose any specifics pertaining to this cooling step (column 3, lines 6-9).

Therefore, Soane is silent as to Applicants' claimed pressure range, holding the substrate and cover at the heating temperature for at least 15 minutes, and cooling for up to 30 seconds down to a temperature of 40°C or about 40°C.

It is known in the art to produce microfluidic devices using an adhesive-free bonding process, where a polymeric substrate having microchannels is bonded to a polymeric cover by the application of heat and pressure, as taught by McReynolds (column 3, lines 15-19 and 40-43;

column 4, lines 24-26 and 33-36). McReynolds acknowledges that the applied temperature and pressure will depend on the nature of the polymeric material (column 4, lines 33-36); it being noted that McReynolds (column 3, lines 41-43) discloses polymers (i.e. polymethyl methacrylate) identical to those of the present invention (claim 45) and Soane (column 9, line 66 – column 10, line 1).

Therefore, selection of a particular pressure range for the process of Soane would have been within purview of the skilled artisan at the time the invention was made depending on the polymeric material used because such is known in the art, as taught by McReynolds, wherein the skilled artisan would have been inclined to select a pressure range that produced a strong bond without deforming the substrate and/or cover.

As for holding the substrate and cover of Soane at the elevated temperature for a specific period of time, it is noted that Soane specifically points out that the temperature is held "for a **time period sufficient** to allow the polymer molecules to interpenetrate the polymeric surfaces of the substrate and cover and create a morphological bonding" (column 3, lines 1-4). The skilled artisan reading the reference as a whole would have readily appreciated that selection of such a time period would have been determined by the polymeric materials used, such that the polymer molecules have sufficient time to interpenetrate the surfaces of the substrate and cover in order to create a satisfactory bond; it being noted that Soane teaches polymeric materials (i.e. polymethyl methacrylate; column 9, line 67 – column 10, line 1) identical to those of the claimed invention (see claim 45).

It is known in the art to bond two polymeric substrates made from the same or different thermoplastic materials (i.e. polymethyl methacrylate; see Table in column 3) using an adhesive-

free bonding process wherein the substrates are pressed together while heating them to a temperature above their glass transition temperatures while applying pressure thereto, as taught by Oshida (abstract; column 1, lines 6-8; column 1, line 30 – column 2, line 5). The substrates are then subjected to "slow cooling" while maintaining the applied pressure, wherein the reference defines "slow cooling" as a cooling speed of about 5°C/sec such that the adjective "slow" refers to the number of degrees the temperature of the substrates is reduced/cooled per unit time and NOT the total amount of time that cooling takes place (column 2, lines 33-36; column 3, lines 5-9). In one example, the reference teaches heating to 110°C (23°C above a glass transition temperature of 87°C) and then cooling to 55°C at a 5°C/sec cooling speed (column 3, lines 25-27); therefore, the skilled artisan would have appreciated that the substrates are cooled for about 11 sec.

The examiner would like to point out that Oshida teaches the substrates undergoing further "natural cooling" upon exposure to room temperature after "slow cooling" has taken place (column 3, lines 28-30); however, the examiner would also like to point out that the present invention teaches "cooling up to 30 seconds" taking place within a cabinet in which the device was heated and then removing the cooled device from the cabinet (p. 4, lines 13-15; p. 5, lines 5-8), wherein the skilled artisan would have appreciated that like the device of Oshida, the device of Soane would also undergo "natural cooling" when removed from the cabinet since it would be exposed to room temperature.

Therefore, it would have been obvious to the skilled artisan at the time of the invention to slowly reduce the temperature of the substrate of Soane using a cooling speed of 5°C/sec such

that cooling takes place for up to 30 seconds because such is know in the art, as taught by Oshida, and it avoids overcooling (Oshida; column 2, lines 34-36).

Oshida teaches cooling down to a temperature lower than the glass transition temperature, preferably to a temperature about 30°C lower than the glass transition temperature (column 2, lines 6-10), while still maintaining the applied pressure on the substrates (column 3, lines 5-9). The reference provides multiple examples including some where the glass transition temperature of the material is 50°C (column 2, lines 42-45) or 87°C (column 3, lines 19-20) and therefore these materials are cooled down to a temperature of 20°C and 55°C, respectively (column 3, lines 25-27; Table in column 3).

The skilled artisan would have readily appreciated that Oshida is not limited to a particular material (see Table in column 3) and therefore use of a material having a glass transition temperature of 70°C or about 70°C would have been very likely wherein such a material would have been cooled down to 40°C or about 40°C; especially since Oshida provides examples using materials that have a cool down temperature very close to that being claimed. More importantly, the skilled artisan would have appreciated that Oshida's desire to cool down to about 30°C below the glass transition temperature is only **preferable** and by no means limiting and therefore the skilled artisan would have chosen to cool down to a particular temperature based on the material being cooled such that sufficient cooling is achieved so as to prevent delamination once the applied pressure is released from the substrates.

Therefore, selection of a particular temperature to cool the substrate and cover of Soane down to would have been within purview of the skilled artisan depending on the materials used such that sufficient cooling is achieved so as to prevent delamination; however, it would have

been obvious to cool down the substrate and cover of Soane to 40°C or about 40°C because the skilled artisan would have appreciated that such is not excluded, and even perhaps suggested, by the teachings of Oshida.

Regarding claims 24, 29, and 45, Soane teaches using polymethyl methacrylate for the substrate and cover (column 9, line 67 – column 10, line 1).

Regarding claims 26-28, Soane teaches the depressions being 50-750 μm (column 1, lines 35-43).

Regarding claims 31-32, Applicants are directed to the rejection of claim 23 set forth above.

Regarding claims 33 and 36, Applicants are directed to the rejection of claim 23 set forth above.

Regarding claim 34, Applicants are directed to the rejection of claim 23 set forth above.

9. Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al., McReynolds, and Oshida et al. as applied to claim 23 above, and further in view of Parce et al. (US 6046056; of record), as set forth in paragraph 7 of the previous office action dated 3/4/04.

Regarding claim 30, Soane is silent as to at least the cover being transparent. It would have been obvious to the skilled artisan at the time the invention was made to use a transparent polymeric cover and/or substrate for those of Soane because such is known in the microfluidic device art, as taught by Parce (column 8, lines 57-66; column 9, lines 7-15), and this enables the microfluidic device to include a visual detection element (Parce; column 8, line 65 – column 9, line 3).

Response to Arguments

10. Applicant's arguments filed 9/2/04 have been fully considered but they are not persuasive.

11. On page 6 of the remarks, Applicant argues that Oshida teaches cooling down to 55°C whereas amended claim 23 states cooling down to 40°C.

Applicant is invited to reread the rejection of claim 23 as set forth above in paragraph 8. The examiner would first like to point out that cooling down to a temperature of 55°C is only one of many examples provided in the Oshida reference.

To reiterate, Oshida teaches cooling down to a temperature lower than the glass transition temperature, preferably to a temperature about 30°C lower than the glass transition temperature (column 2, lines 6-10), while still maintaining the applied pressure on the substrates (column 3, lines 5-9). The reference provides multiple examples including some where the glass transition temperature of the material is 50°C (column 2, lines 42-45) or 87°C (column 3, lines 19-20) and therefore these materials are cooled down to a temperature of 20°C and 55°C, respectively (column 3, lines 25-27; Table in column 3).

The skilled artisan would have readily appreciated that Oshida is not limited to a particular material (see Table in column 3) and therefore use of a material having a glass transition temperature of 70°C would have been very likely wherein such a material would have been cooled down to 40°C; especially since Oshida provides examples using materials that have a cool down temperature very close to that being claimed. More importantly, the skilled artisan would have appreciated that Oshida's desire to cool down to about 30°C below the glass transition temperature is only **preferable** and by no means limiting and therefore the skilled

artisan would have chosen to cool down to a particular temperature based on the material being cooled such that sufficient cooling is achieved so as to prevent delamination once the applied pressure is released from the substrates.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jessica L. Rossi** whose telephone number is **571-272-1223**. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine R. Copenheaver can be reached on 571-272-1156. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Rossi
Art Unit 1733